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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/647,522

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Daniel C. Sigg

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/647,522	Applicant(s) SIGG ET AL.	
	Examiner CHRISTOPHER D. KOHARSKI	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 18-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-17 and 42-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Amendment***

Examiner acknowledges the reply in which claim 1 was amended and new claims 42-47 were added. Currently claims 1-47 are pending for examination with claims 9 and 18-41 withdrawn from a previous election restriction. Examiner acknowledges the amendments made to the specification and drawings.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 11 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner asserts that the subsequent dependant claims disclose "...an electrical stimulus to the tissue...", Applicant is defining a new electrical stimulus in addition to the already claimed stimulus in independent claim 1, which is unsupported by the present disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-8, 10-13, 15, 17, 42-44 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Abele et al. (USPN5,403,311). Abele et al. discloses an electro-coagulation and ablation and other electro therapeutic body tissue treatments.

Regarding claims 1-8, 10-13, 15, 17, 42-44 and 47, a catheter (Figures 3A-10) comprising: a catheter (54) body that defines an inner lumen; an extendable probe (56) within the inner lumen that delivers fluid (macromolecules) to a tissue site of a patient (col 3, ln 30-55) with an exit (tip of 56, 39); at least one electrode (58, 60) (or second, Figure 10) coupled to the catheter to detect contact between the catheter and the tissue site (col 9, ln 1-45); and an electrical stimulus to the tissue site is delivered through the at least one electrode and the probe (col 9, ln 30-55) (cols 1-2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 13 is rejected under 35 U.S.C 103(a) as being unpatentable over Abele et al. in view of Mulier et al. (5,807,395). Abele et al. meets the claim limitations as described above except for the electrode used for cardiac pacing.

However, Mulier et al. teaches a apparatus for RF ablation.

Regarding claim 13, Mulier et al. teaches a catheter (1) with a distal tip electrode (3) that is used for cardiac ablation and is disclosed as also being employed for measurement functions or pacing of heart tissue by application of low energy electrical stimuli (Figure 1) (col 6, ln 20-55).

At the time of the invention, it would have been obvious to use the teachings of Mulier to use the electrode of Abele et al. for cardiac pacing in order to better treat the patient in conjunction with the active drug treatment. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Mulier et al. (cols 3-4).

Claim Rejections - 35 USC § 103

Claims 16 and 45 are rejected under 35 U.S.C 103(a) as being unpatentable over Abele et al. in view of Epstein et al. (USPN6,835,193). Abele et al. meets the claim limitations as described above except for the delivery of specific macromolecules such as DNA, RNA, etc..

However, Epstein et al. teaches a device and method for controlled depth injections.

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Regarding claims 16 and 45, Epstein et al. discloses a catheter comprising a catheter body (2) that defines an inner lumen (near 16); a probe (14) with a needle tip within the inner lumen that delivers fluid (from 400) to a tissue site of a patient; and at least one electrode (35) coupled to the catheter to detect contact between the catheter and the tissue site. The catheter body (2) is capable of guiding the probe (14) to a tissue site with the probe being retractable and extendable (Figures 3-4) through a distal port (10) to deliver multiple therapeutic macromolecule compounds such as DNA (cols 2 and 17) (Figures 1-6).

At the time of the invention, it would have been obvious to add the therapeutic agents of Epstein et al. in order to aid in further tissue treatment. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Epstein et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claim 46 is rejected under 35 U.S.C 103(a) as being unpatentable over Adele et al. in view of Moorehead (USPN5,147,332). Adele et al. meets the claim limitations as described above except for the pressure response exit port valves.

However, Moorehead teaches a multi-valve infusion catheter.

Regarding claim 46, Moorehead teaches a catheter device (Figure 2) used for infusion (Figure 1) comprising several distal end pressure responsive exit valves (16, 18).

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At the time of the invention, it would have been obvious to add the distal end valves of Moorehead to the system of Adele et al. in order to control the infusion rate within the patient or prevent agent backflow. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Moorehead (cols 1-2).

Response to Arguments

Applicant's arguments with respect to claims 1-8,10-17 and 42-47 have been considered but are moot in view of the new ground(s) of rejection.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further clarification of distal end electrode assembly in reference to function and structure of the electrode/probe assembly (see Figure 3).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is

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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 5/23/2008

/Christopher D Koharski/
Examiner, Art Unit 3763/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763